

**REMARKS**

**Formal Matters**

Claims 22-38 are pending after entry of the amendments set forth herein.

Claims 22-38 were examined. Claims 22-38 were rejected.

**Rejection under 35 U.S.C. §103**

The pending claims 22-38 were rejected under 35 U.S.C. §103 as unpatentable over Schenk et al. (WO 90/07351) in view of Velasquez et al. ('548). The rejection is traversed in view of the comments put forth below.

Applicant is claiming a method of treating diabetes. Schenk et al. is not discussing, disclosing or contemplating the treatment of diabetes nor is the secondary reference to Velasquez et al. which merely lists insulin among many other drugs. Within applicant's method applicant claims a specific range with respect to the amount of insulin absorbed into the blood stream of the patient in terms of units of insulin. Based on the amount of insulin aerosolized and delivered to the patient by inhalation these concepts are not discussed contemplated or obvious in any manner in view of Schenk et al.

Within claim 24 applicant claims a method of regulating the blood glucose levels. Schenk et al. does not discuss, contemplate or in any manner render obvious methods of regulating blood glucose levels. Applicant specifically claims repeating steps periodically as needed in order to regulate the patient's blood glucose levels. Such is not discussed, disclosed or in any way rendered obvious in view of Schenk et al and, again Velasquez et al. merely lists insulin among many drugs and teach no method steps.

Within claim 25 applicant also claims a method of regulating blood glucose levels. Schenk et al. is not concerned with regulating blood glucose levels, and does not disclose or render obvious any such method. Further, applicant's method includes supplying a fixed quantity of dry insulin powder. Schenk et al. does not disclose such. Applicant has specifically claimed flowing at least a portion of the aerosolized suspension through a mouthpiece in a manner which causes the patient to absorb into the patient's blood stream a controlled quantity of insulin to achieve acceptable blood glucose levels following treatment. This is not disclosed or rendered obvious in view of Schenk et al.

Within claim 27 applicant claims a method of administering a sufficient amount of insulin to a patient to achieve blood glucose control. In claim 31 applicant claims a method of lowering a patient's serum glucose levels to an acceptable value. In claim 32 applicant claims administering a controlled and

repeatable dose of insulin to produce an acceptable serum glucose level in a diabetic patient. In claim 35 applicant claims administering insulin to a diabetic patient to control serum glucose levels via a hand held inhalation device. These independent claims also claim additional features with respect to specific method steps and/or amounts which are not disclosed, discussed or rendered obvious in view of Schenk et al.

The rejection has cited Velasquez for its disclosure of insulin. Applicant's review of the patent shows that the word "insulin" is put forth at col. 6, line 32 of Velasquez et al. However, there is no discussion of any of the general methods claimed by applicant, no discussion of treating diabetes, maintaining serum glucose levels or administering a controlled and repeatable dose of insulin. Accordingly, the combined references do not teach the specifically claimed method steps.

In deciding the question of obviousness under 35 U.S.C. §103, it is not realistic to pick and choose from any one reference only so much of it as will support a given position, to the exclusion of other parts necessary to the full appreciation of what such a reference barely suggests to one of ordinary skill in the art. Here, Schenk et al. discloses general methodology with respect to the inhalation of drugs. It does not disclose specific methodology with respect to any of the methods claimed by applicant. It specifically does not disclose insulin or treating diabetes or maintaining glucose levels. Further, nothing within the disclosure provides sufficient teachings which would allow one skilled in the art to utilize the technology to administer insulin in an effective and safe manner so as to treat a diabetic patient.

Applicant recognizes that the rejection has cited Velasquez for its disclosure of insulin. However, the mere existence in the prior art of individual features of a claimed invention does not, without more, render that invention obvious within the meaning of 35 U.S.C. §103. Here, Velasquez does nothing more than list the word "insulin" among many other potential pharmaceuticals. Nothing within Velasquez et al. suggests that it might be combined with Schenk et al. in any manner let alone in some manner which would provide for applicant's specifically claimed methods. There must be positive evidence of how the bringing together of the disclosed features or steps would be obvious to an ordinarily skilled person in order to provide for a rejection under 35 U.S.C. §103.

Essentially no invention would be patentable if a rejection could, after disclosed and claimed, be subjected to rejections based on combining the prior art and piecing together portions of earlier patents while dropping other parts to put together the particular combination claimed by applicant. Here, the

rejection simply does not explain how to effectively and safely treat a patient using the inhalation of insulin. In view of such applicant respectfully requests reconsideration and withdrawal of the rejection.

The relative insulin requirements, specific amount ranges, and steps claimed by applicant is important in terms of obtaining a safe and effective manner of treating patients and maintaining safe blood glucose levels. These steps and ranges are not taught within the cited references. Even assuming arguendo that the references showed the claimed elements (and they do not) the rejection has not presented a line of reasoning as to why the artisan viewing only the collective teachings of the references would have found it obvious to selectively pick and choose the insulin from Velasquez et al. among the various other drugs disclosed within that reference to combine it with Schenk et al. to obtain the method claimed by applicant. To obtain applicant's invention multiple modifications and variations of Schenk et al. would be necessary even if the insulin component of Velasquez et al. were combined with Schenk et al. Accordingly, the combination of the references is not obvious and even if made does not render obvious the claimed invention.

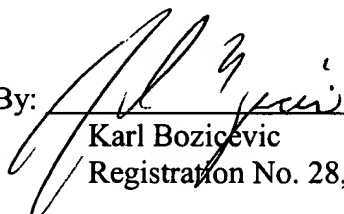
### Conclusion

Applicant submits that all of the claims are in condition for allowance, which action is requested. If the Examiner finds that a telephone conference would expedite the prosecution of this application, please telephone the undersigned at the number provided.

The Commissioner is hereby authorized to charge any underpayment of fees associated with this communication, including any necessary fees for extensions of time, or credit any overpayment to Deposit Account No. 50-0815, order number AERX-058CON3.

Respectfully submitted,  
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Date: 16/JUNE/03

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